Effects of the Initial Platelet Value on the Outcomes of Patients in the Pediatric Intensive Care Unit

Çocuk Yoğun Bakım Ünitesinde Başvuru Trombosit Değerinin Hasta Sağkalımına Etkisi

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ABSTRACT

Objective: Thrombocytopenia is a common haematological finding in critically ill patients. Studies have shown that decreased platelet counts are associated with prolonged hospitalisation, increased costs, and mortality in adult populations. However, not enough studies have investigated the incidence of thrombocytopenia and the relationship between thrombocytopenia and the prognoses of paediatric patients who require treatment in the intensive care unit. We evaluated the effects of initial platelet counts on the outcomes of pediatric intensive care unit patients.

Material and Methods: We performed a retrospective analysis of the records of all patients admitted to the pediatric intensive care unit between October 2016 and December 2017. The relationship between the initial thrombocyte counts and the need of invasive mechanical ventilation and non-invasive mechanical ventilation, inotropic drug use, continuous renal replacement need, duration of hospitalization and mortality rate were investigated.

Results: Totally 387 patients were included in the study. Patient ages ranged from 1 month to 17 years, and the most frequent diagnoses were respiratory diseases (144 patients; 37.2%). There was a statistically significant relationship between thrombocyte levels of the first complete blood count performed during admission and invasive mechanical ventilation, non-invasive mechanical ventilation, inotropic drug use, mortality, acute kidney injury, and continuous renal replacement therapy. The odds ratios (ORs) and relationship between prognostic factors and thrombocytopenia were calculated using logistic regression models. ORs were 4.616 for continuous renal replasman therapy, 6.682 for inotropic drug use, and 3.649 for mortality. The survival analysis revealed that lower platelet counts were associated with poorer survival.

Conclusion: A low platelet count at the time of admission to the PICU should be considered an independent risk factor that increases mortality and morbidity and prolongs hospitalisation. Extensive care should be provided to this group of patients.

Key Words: Critically ill children, Prognosis, Thrombocytopenia

ÖΖ

Amaç: Trombositopeni, kritik hastalardaki ortak bir hematolojik bulgudur. Araştırmalar, trombosit sayısındaki azalmanın, hastanede yatış süresinin uzaması, artan maliyetler ve yetişkin popülasyonunda mortalite ile ilişkili olduğunu göstermiştir. Ancak, trombositopeninin görülme sıklığını ve trombositopeni ile yoğun bakım ünitesinde tedavi gerektiren pediatrik hastaların prognozları arasındaki ilişkiyi araştıran yeterli çalışma yoktur. Başvuru trombosit sayısının çocuk yoğun bakım ünitesi hastalarındaki sonuçlarını değerlendirdik.

Gereç ve Yöntemler: Çocuk yoğun bakım ünitesine Ekim 2016 - Aralık 2017 tarihleri arasında başvuran tüm hastaların kayıtlarının geriye dönük olarak inceledik. Başvuru trombosit sayıları ile invaziv mekanik ventilasyon ihtiyacı ve non-invaziv mekanik ventilasyon ihtiyacı, inotropik ilaç kullanımı arasındaki ilişki, sürekli renal replasman ihtiyacı, hastanede yatış süresi ve mortalite oranları araştırıldı.

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Received / Geliş tarihi : 26.02.2019 Accepted / Kabul tarihi : 28.06.2019 Online published : 14.05.2020 Elektronik yayın tarihi DOI: 10.12956/tchd.532433 **Bulgular:** Çalışmaya toplam 387 hasta dahil edildi. Yaş dağılımları 1 ay ile 17 yıl arasında değişmekte olup, ortalama hasta yaşı 3.95 ± 4.80'di. Hastaların en sık başvuru tanısı solunum sıkıntısıydı (144 hasta;% 37.2). Başvuru sırasındaki ilk tam kan sayımı trombosit seviyeleri ile invaziv mekanik ventilasyon, invaziv olmayan mekanik ventilasyon, inotropik ilaç kullanımı, mortalite, akut böbrek hasarı ve sürekli böbrek replasman tedavisi arasında istatistiksel olarak anlamlı bir ilişki vardı. Trombosit sayısı için receiver-operator characteristic (ROC) eğrilerinin analizi, 102.000'lik bir kesim değerinde ölüm oranının% 92.7 duyarlılığa ve % 53.1 özgüllüğe sahip olduğunu göstermiştir. Odds oranları (OR'ler), prognostik faktörler ve trombositopeni ile arasındaki ilişki lojistik regresyon modelleri kullanılarak hesaplandı. ORs sürekli renal replasman tedavisi için 4.616, inotropik ilaç kullanımı için 6.682 ve mortalite için 3.649'du.

Sonuç: Çocuk yoğun bakıma yatış sırasındaki düşük trombosit sayısı, mortalite ve morbiditeyi artıran ve hastanede yatış süresini uzatan bağımsız bir risk faktörü olarak düşünülmelidir. Bu hasta grubuna daha yakın izlem yapılmalıdır.

Anahtar Sözcükler: Kritik çocuk hasta, Prognoz, Trombositopeni

INTRODUCTION

Scoring systems such as Pediatric Logistic Organ Dysfunction (PELOD) and Pediatric Risk of Mortality (PRISM) were developed to objectively evaluate the prognosis and mortality of critically ill children (1). Platelet count is one of the PRISM score parameters. Thrombocytopenia is a common hematological finding in critically ill patients that can be observed in the blood parameters of pediatric intensive care unit (PICU) patients due to sepsis, haemolysis, or bleeding. Studies have shown that decreased platelet counts are associated with prolonged intensive care unit (ICU) hospitalizations, increased costs, and mortality in adult populations (2,3). It has also been revealed that platelet values can be used to determine prognoses (2-4). However, few studies have investigated the incidence of thrombocytopenia and the relationship between thrombocytopenia and the prognoses of pediatric patients who require treatment in the PICU. This study evaluated the relationship between platelet count and prognosis on admission to the PICU.

MATERIAL and **METHODS**

Study Design

We performed a retrospective analysis of the records of all patients admitted to the PICU between October 2016 and December 2017. Our tertiary, multidisciplinary PICU is located in a training and research hospital, and it provides health care for children from 1 month to 18 years of age. It has 12 beds, 11 ventilators, and two isolation rooms. A paediatric intensive care specialist, two assistants, and 27 nurses provide care.

All clinical investigations were conducted according to the principles expressed in the Declaration of Helsinki. The retrospective protocol of this study was approved by the institutional ethics committee (Health Sciences University, Okmeydani Training and Research Hospital, Ethics Committee, no: 2017-763; November 21, 2017). All study-related anonymized data, computer codes, and protocols are available on reasonable request.

Patient Population and Data Collection

Electronic and medical records were retrospectively searched to collect data. We excluded patients with a PICU stay <24

h, patients who died during the first day after admission, and patients with hematological and oncological diseases. Demographic data, reason for hospitalisation, underlying chronic diseases, and initial platelet counts were recorded. To obtain hemogram measurements, peripheral blood was collected in an EDTA vacutainer tube and analysed by an automated blood cell counter (Cell-Dyn 3700; Abbott Laboratories, Chicago, IL, USA). Approval was obtained from the local ethics committee (2017-763).

The relationships between the initial platelet counts and invasive mechanical ventilation (IMV) support, noninvasive mechanical ventilation (NIV) support, the need for inotropic drugs, acute kidney injury (AKI) development, continuous renal replacement therapy (CRRT), sepsis, thrombocytopenia-associated multiple organ failure (TAMOF), and mortality were evaluated.

Patients were divided into three groups according to the thrombocytopenia status and compared regarding prognoses. Thrombocytopenia was defined as a platelet count <150.000/mm³. The severity of thrombocytopenia was classified as mild (platelet count 100.000/mm³ to 149.000/mm³), moderate (platelet count 50.000 to 99.000/mm³), or severe (platelet count <50.000/mm³) (5). Platelet counts were correlated with the PRISM score, as shown in the boxplot graphic (Figure 4).

The PRISM III score was calculated using the lowest and highest systolic blood pressure values during the first 24 hours for each patient and the diastolic blood pressure, heart rate and respiratory rate per minute, PaO₂/FiO₂, PaCO₂, calcium, potassium, glucose, bicarbonate level, pupillary response, Glasgow coma score, prothrombin time-partial thromboplastin time, and serum total bilirubin.

Acute kidney injury was defined as oliguria (urine output <0.5 ml/kg/h) and increased serum creatinine level based on the patient's age or 1.5-fold increase in basal creatinine level within 24 hours. The estimated glomerular filtration rate was calculated according to the original Schwartz formula. Additionally, when measuring serum urea and creatinine levels, the glomerular filtration rate was measured routinely by our laboratory using a scale. Patients with sepsis or septic shock were diagnosed according to the Surviving Sepsis Campaign Guidelines (6).

Statistical Analysis

The SPSS program (version 21.0; IBM, SPSS Inc., Chicago, IL, USA) was used for statistical analyses. Numerical data were expressed as mean ± standard deviation. Categorical

data were expressed as frequency (n) and percentage (%). Differences between the two groups were analysed by oneway analysis of variance (ANOVA). The Pearson test was used to correlate two continuous variables with normal distribution. The receiver-operator characteristic (ROC) curve was used to assess the thrombocyte count, prognostic factors, and mortality. Multivariate binary logistic regression models were used to calculate the odds ratios (ORs) and 95% confidence interval (Cls) for prognoses. Survival data were calculated using the Kaplan-Meier log-rank statistical analysis. Statistical significance was accepted as p<0.05.

The cut-off and area under the curve (AUC) values were interpreted using the ROC analysis in accordance with the methods of Dirican et al (7). An AUC value of 0.5 corresponded to random chance, and an AUC value of 1.0 indicated perfect accuracy of the ROC curve (8, 9).

RESULTS

Demographics

Records of 387 patients were included in the study (Figure 1). The demographic characteristics of the patients are shown in Table I. There were 210 (54.3%) male patients and 177 (45.7%) female patients. Age distributions ranged from 1 month to 17 years, and the mean patient age was 3.95±4.80 years. The most frequent diagnoses of patients were respiratory system diseases (144 patients; 37.2%), and the other diagnoses were neurological disease, sepsis, and intoxication. The most common cause of respiratory system diseases was lower respiratory tract infections such as bacterial and viral pneumonia (109 patients). The mean duration of the PICU stay was 7.17±10.63 days. IMV was used for 111 (28.9%) patients, and NIV was used for 168 (43.5%) patients. After extubation, NIV was used for 56 patients. AKI developed in 96 (24.8%) patients during the PICU stay, and 46 of these patients underwent CRRT. The remaining patients were administered supportive treatments. Peritoneal dialysis and intermittent dialysis were not performed. Dobutamine (27 patients) and milricor (29 patients) were also used. Eighty-nine (23.0%) patients were treated with inotropic drugs. The most commonly used inotropic drug was noradrenaline (72 patients). Extracorporeal membrane oxygenation (ECMO) was performed for six patients. Fourteen of the patients (3.6%) were lost during the PICU stay.

Prognostic factors associated with thrombocyte count

There was a statistically significant relationship between thrombocyte levels of the first complete blood count performed during admission and IMV support (p=0.010), NIV support

No. of patients	n=387 n (%)/Mean ± SD				
Sex	210 (54,3%)				
Male Female	177 (45.7%)				
Reason for hospitalisation					
Respiratory system disease	144 (37.2%)				
Cardiovascular disease	19 (4.9%)				
Neurologic disease	64 (16.5%)				
Sepsis	58 (15.0%)				
	40 (10.3%)				
Irauma	15 (3.9%)				
Age	1 month to 17 years (3.95±4.80 years)				
Acute kidney injury	96 (24.8%)				
Inotropic medication	89 (23.0%)				
CRRT	46 (11.9%)				
IMV	111 (28.9%)				
Duration of stay in the PICU, days	7.17±10.63				
Central venous catheter	235 (60.7%)				
ECMO	6 (1.6%)				
PRISM III	17.20±13.77				
Mortality	14 (3.6%)				
NIV	168 (43.5%)				
Thrombocyte count <100.000/mm ³	30 (7.8%)				

CRRT: Continuous renal replacement therapy; **IMV:** invasive mechanical ventilation; **PICU:** paediatric intensive care unit; **ECMO:** extracorporeal membrane oxygenation; **PRISM:** Pediatric Risk of Mortality score; **NIV:** noninvasive mechanical ventilation

Table II: Prognostic Factors and Thrombocyte Count.						
	Thrombocytes (mm ³)	р				
IMV support Yes No	302.688±189.273 365.397±169.490	0.010				
NIV support Yes No	385.434±191.598 312.498±157.322	<0.001				
Inotropic medication Yes No	280.566±198.932 367.894±165.176	<0.001				
Mortality Yes No	233.000±188.008 352.420±175.502	0.023				
Acute kidney injury Yes No	260.931±208.573 364.236±165.384	<0.001				
Continuous renal replacement therapy Yes No	164.125±116.233 359.288±174.283	<0.001				
Duration of stay in PICU 7 days or less More than 7 days	341.256±162.243 334.546±208.702	0.780				

IMV: Invasive mechanical ventilation; NIV: Noninvasive mechanical ventilation; PICU: Pediatric intensive care unit

Table III: Comparison of Prognostic Factors for Thrombocytopenic Patients and Non-Thrombocytopenic Patients.							
	Thrombocyte count						
	<50.000 mm³ (n=8)	50-100.000 mm ³ (n=22)	>100.000 mm³ (n=355)	р			
Sex Male Female	6 (75.0%) 2 (25.0%)	13 (59.1%) 9 (40.9%)	184 (51.8%) 171 (48.2%)	0.356			
Age, year	4.56±4.50	5.46±5.19	3.56±4.34	0.181			
IMV support	7 (87.5%)	9 (40.9%)	95 (26.7%)	<0.001			
Inotropic medication	7 (87.5%)	15 (68.2%)	67 (18.9%)	<0.001			
Acute kidney injury	8 (100%)	13 (59.1%)	75 (21.1%)	<0.001			
Continuous renal replacement therapy	5 (62.5%)	9 (40.9%)	32 (9.0%)	<0.001			
NIV support	4 (50.0%)	6 (46.3%)	158 (43.1%)	0.161			
Mortality	4 (50.0%)	4 (18.2%)	6 (1.7%)	<0.001			
Duration of stay in PICU >7 days	3 (37.5%)	11 (50.0%)	125 (35.2%)	0.111			
Duration of stay	14.75±12.41	8.90±13.66	7.64±10.55	0.169			
PRISM III	40.00±9.47	25.06±21.10	12.36±10.12	< 0.001			
Sepsis	5 (62.5%)	13 (59.1%)	40 (11.3%)	<0.001			
TAMOF	5 (62.5%)	15 (68.2%)	14 (3.9%)	< 0.001			

IMV: Invasive mechanical ventilation; NIV: noninvasive mechanical ventilation; PIC: pediatric intensive care unit; PRISM: Pediatric Risk of Mortality score; TAMOF: thrombocytopenia-associated multiple organ failure

(p<0.001), inotropic drug use (p<0.001), mortality (p=0.023), AKI (p<0.001), and CRRT (p<0.001) (Table II).

Patients were divided into three groups according to the thrombocytopenia status (Table III). There was no statistically significant difference in terms of age and sex when comparing patients with and without thrombocytopenia. IMV (p<0.001), inotropic drug use (p<0.001), mortality (p<0.001), PRISM III score (p<0.001), AKI (p<0.001), the need for CRRT (p<0.001), sepsis (p<0.001), and TAMOF (p<0.001) were statistically higher in the thrombocytopenic groups (Table III).

Table IV: ROC Analysis of Prognostic Factors for PICU Patients.

	AUC	SE	р	95% CI		0.1.5%		
Parameter				Lower Limit	Upper Limit	Value	Sensitivity	Specificity
AKI	0.692	0.037	<0.001	0.619	0.766	265.000	72.8%	61.4%
CRRT	0.825	0.038	<0.001	0.750	0.901	146.000	90.3%	55.9%
IMV support	0.584	0.033	0.013	0.519	0.659	148.000	90.1%	23.9%
Inotropic drug use	0.669	0.036	<0.001	0.598	0.741	152.000	93.2%	36.9%
Duration of stay >7 days	0.481	0.032	0.533	0.419	0.543	334.500	46.1%	51.6%
Mortality	0.822	0.077	< 0.001	0.671	0.974	102.000	92.7%	53.1%

AKI: acute kidney injury; CRRT: Continuous renal replacement therapy; IMV: Invasive mechanical ventilation

Table V: Logistic Regression Analysis of Prognostic Factors for Thrombocytopenic Patients.

Risk	р	Odds Ratio	95% Confidence Interval
Acute kidney injury	0.201	2.072	0.678-6.334
Continuous renal replacement therapy	0.007	4.616	1.526-13.967
Invasive mechanical ventilation	0.765	0.637	0.430-3.969
Noninvasive mechanical ventilation	0.994	0.997	0.451-2.204
Inotropic drug use	0.002	6.682	2.010-22.213
Mortality	0.012	3.649	0.734-12.979

Analysis of ROC curves of the correlation between platelet counts and prognostic factors

Analyses of ROC curves for the thrombocyte counts showed that with a cut-off value of 153.500, mortality had 83.1% sensitivity and 79.2% specificity, AKI had 72.8% sensitivity and 61.4% specificity, CRRT had 90.3% sensitivity and 55.9% specificity, IMV support had 63.2% sensitivity and 51.4% specificity, and inotrope use had 70.3% sensitivity and 58.6% specificity. Duration of stay had low sensitivity and specificity (Table IV). The relationship between the thrombocyte count and mortality is shown in Figure 2. Determination of the PRISM III score using the ROC curve is shown in Figure 3. Patients were divided into four groups according to their platelet counts. Those with lower platelet counts had higher PRISM III scores, as seen in the boxplot graphic (Figure 4).

Logistic regression analysis of prognostic factors in terms of platelet counts

The ORs and relationship between prognostic factors and thrombocytopenia were calculated using logistic regression models. ORs were 2.072 (Cl, 0.678-6.334) for acute kidney injury, 6.682 (Cl, 1.896-13.962) for inotropic drug use, and 3.649 (Cl, 0.734-12.979) for mortality (Table V).

Survival data from the Kaplan-Meier survival analysis

The Kaplan–Meier log-rank statistic performed to determine the survival distribution regarding platelet counts <100.000 and mortality during the PICU stay indicated a significant difference between groups (p < 0.001) (Figure 4).

DISCUSSION

This study evaluated the effects of initial platelet counts on the outcomes of paediatric intensive care unit (PICU) patients. We found that a low platelet count at the time of admission to the PICU should be considered an independent risk factor that increases mortality and morbidity and prolongs hospitalization.

Thrombocytes are blood elements that occur during the first phase of haemostasis. In healthy people, bone marrow megakaryocytes produce 150 billion platelets per day, and the average life span of platelets is 10 days. The peripheral thrombocyte count is controlled by thrombopoietin, which regulates platelet production in bone marrow, platelet pools in the liver and spleen, and the reticuloendothelial system (10,11). Therefore, we did not include hematology and oncology patients in our study.

Thrombocytopenia, which is the most common cause of bleeding, is a haematological disorder frequently encountered in hospitalised patients. Sepsis is among these hematological disorders (5,6). During sepsis, platelets accumulate in the inflammation pathway, thus leading to microcirculation deterioration and organ dysfunction. However, beneficial effects of platelets during sepsis include reduced vascular permeability and contributions to the inflammatory process, host defence mechanisms, and wound healing (12,13). In our study, 58 (15%) patients had sepsis. An additional five



Figure 1: Cohort flow.



Figure 3: Comparison of ROC curves of PRISM III scores to determine mortality in the PICU.

of eight severe thrombocytopenia patients had sepsis. Two of the five patients with severe thrombocytopenia died. They had late-stage meningococcemia and were administered ECMO. Furthermore, the incidence rates of sepsis and TAMOF in the thrombocytopenia group in our study were statistically significantly high. Kaur et al. (14) reported that thrombocytopenia was commonly associated with sepsis and mortality rate was higher in these patients.

In the literature, the incidence of thrombocytopenia in PICU patients ranges from 13% to 58% (15,16). This difference is explained by the various study populations, inclusion criteria, and different definitions of thrombocytopenia. In our study, the incidence of thrombocytopenia was 10.6%, which may



Figure 2: Comparison of ROC curves of thrombocyte counts to determine mortality in the PICU.

have been due to the exclusion of haematology and oncology patients. Moreover, the majority of our patients had a lower respiratory tract infection. The heterogeneity of the patients in our study may be useful for reflecting the pediatric population.

Although platelet counts are constant in healthy people, the disturbances that can occur in defined mechanisms in critically ill patients may cause an imbalance in platelet production, platelet pooling, and platelet consumption, thus leading to thrombocytopenia (17). Thrombocytopenia in critically ill patients is associated with increased bleeding episodes that lead to the need for transfusions of fresh-frozen plasma, platelets, and antithrombin III, resulting in prolonged hospitalisation (5,11,17). The ROC analysis showed that thrombocytopenia was not associated with the length of the PICU stay (AUC, 0.481). However, patients in the thrombocytopenia group had longer lengths of stay in the PICU. Underlying diseases in thrombocytopenia patients may have caused this difference. However, another reason could have been the decrease in the length of hospitalization of the patients who died during the early period, such as those in the severe thrombocytopenia group.

Strauss et al. (15) reported that thrombocytopenia is an independent risk factor for the mortality of critically ill patients. Thrombocytopenia is commonly associated with sepsis. Mortality rate is higher in thrombocytopenic patients. One review that included eight studies reported that thrombocytopenia causes increased mortality and should be evaluated as a sensitive indicator of the prognosis for adults (18). However, not enough studies have evaluated the effects of thrombocytopenia on the prognosis of patients in the PICU, especially in Turkey.

In studies involving adults, the mortality scores and platelet counts were correlated (19). In our study, mortality was significantly higher for patients with thrombocytopenia. Eight of



Figure 4: Correlation between the platelet stages and PRISM III scores in the boxplot graphic.

fourteen patients who died had a platelet count <100.000/mm³, and the mortality rate of the severe thrombocytopenia group was 50% (Figure 1). Furthermore, patients with thrombocytopenia during admission had significantly higher PRISM III scores and longer ICU stays. The ROC analysis showed that the thrombocyte count was associated with mortality, similar to the PRISM III curve. Patients with lower platelet counts presented in the boxplot graphic had higher PRISM III scores. Furthermore, the logistic regression analysis showed that thrombocytopenia increased mortality by 3.649-fold. Finally, the survival analysis revealed that lower platelet counts were associated with poorer survival. Patients with thrombocytopenia died earlier than other patients.

It has been mentioned that the use of inotropic drugs is a sign of mortality and poor prognoses (20). In our study, patients who were treated with inotropic drugs had significantly lower initial platelet counts than those who did not have inotropic support (OR, 6.682). The inotropic drug requirement was also greater for patients with thrombocytopenia. Sepsis and septic shock are associated with thrombocytopenia; therefore, septic shock can increase the need for inotropic drug usage (5).

Furthermore, inotropic drug use for AKI is known to be an independent risk factor for poor prognosis in PICU patients (21). In addition, thrombocytopenia is common in patients receiving CRRT (22). In our study, the initial thrombocyte levels were statistically significantly lower in patients with AKI, and a low platelet count at admission was a risk factor for CRRT usage. This suggested that different factors such as platelet counts can be important factors affecting the CRRT requirements in the PICU. Although three patients with haemolytic uremic syndrome were considered haemotologic patients and not included in the study, AKI frequency and CRRT use were still found to be higher in the thrombocytopenia group. The AUC



Figure 5: Kaplan–Meier curves for survival according to platelet counts.

for predicting AKI was 0.692, and that for predicting CRRT was 0.825. This suggested that factors other than AKI can affect the CRRT requirements for platelet counts.

The need for mechanical ventilation support is another risk factor associated with poor prognoses of PICU patients (23). The respiratory, heart, sepsis, and neurological diseases were found to be the major underlying conditions for IMV usage in our study. Initial platelet levels were significantly lower in patients requiring IMV and NIV. The need for IMV support was also greater in the thrombocytopenia group. However, this relationship has not been demonstrated in multivariate logistic regression analyses (OR, 0.637). In the ROC analysis, the AUC (0.584) for IMV was low.

Our study had some limitations. First, this is a retrospective, single-center, observational study with a limited number of patients. Second, platelet transfusions were not recorded after admission. Third, we could not include all laboratory results, such as lymphocyte counts. Fourth, serial measurements of the platelet values were missing. However, a few studies have examined the relationship between the platelet count and mortality in the PICU, especially in Turkey. This was the major strength of our study.

CONCLUSION

In conclusion, a low platelet count at the time of admission to the PICU should be considered an independent risk factor that increases mortality and morbidity and prolongs hospitalisation. Additionally, the initial platelet count can be used as a simple and independent risk factor for the mortality of PICU patients. Extensive care should be provided to these patients.

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